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09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

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PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A.  
4800 IDS CENTER  
80 SOUTH 8TH STREET  
MINNEAPOLIS, MN 55402-2100

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/186,810

Applicant(s)

CARLYLE ET AL.

Examiner

Paul B. Prebilit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8-17 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-13 and 15-17 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27, 2001 has been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3, 4, 8-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan discloses medical devices/implants where the crosslinking agent glutaraldehyde attaches the growth factor biomolecule and to the spacer; see the whole document, especially column 4, lines 20-43 and column 6, lines 8-28. Cahalan's solid surface can be made of human or animal tissues, but Cahalan lacks the types of tissues claimed.

4. However, Goldstein teaches that it was known to make similar medical devices/implants out of heart valves, pericardial tissue and the like; see the whole document, especially column 3, lines 14-24.

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5. Therefore, it is the Examiner's position that it would have been obvious to use heart valve or pericardial tissue for Cahalan's solid surface in order to reduce the risk of disease transmission and cost over using human animal tissue. Furthermore, it would have been obvious to use these tissues for the same reasons that Goldstein desires the same.

6. With regard to claim 12 specifically, the bioresorbable materials are the materials of Cahalan which are bioresorbable such as tissues and hydroxyapatite.

7. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al and Goldstein as applied to claims 1, 3, 4, 8-12 and 15 above, and further in view of Bayne et al (EP 0476983).

8. With regard to claim 13, Cahalan fails to disclose the VEGF claimed even though it discloses many other growth factors therewith. Bayne teaches that it was known to use VEGF as the growth factor in a similar fashion within the same art; see the whole document.

9. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan so that the implant could be successfully implanted in vascular regions of the body.

10. With regard to claim 16, Cahalan/Goldstein fails to disclose the use of endothelial cells therewith, but Goldstein teaches using fibroblasts which can be differentiated to any cell type. However, Bayne teaches that it was known to attach and culture endothelial cells onto an implant to make it more biocompatible; see the whole

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document. Hence, it is the Examiner's position that it would have been obvious to culture endothelial cells onto Cahalan's implant in order to make it more biocompatible.

***Allowable Subject Matter***

11. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claim 28 is allowed over the prior art of record.

***Response to Arguments***

13. Applicant's arguments filed November 13, 2001 have been fully considered but they are not persuasive. However, the arguments, with respect to the Rodman rejection, were persuasive and for these reasons, the rejection of claim 28 has been withdrawn. Similarly, the rejection of claims 1, 3, 4, 8, 9, 11, 12, and 15 under Section 102 has been withdrawn; these claims are now subject to a new rejection under Section 103.

14. Applicant traverses the claim 10 rejection by arguing that there is no motivation to combine Cahalan and Goldstein. However, the motivation is clearly provided in the rejection. Furthermore, Goldstein provides a motivation for using the same tissues even if only implied because Goldstein is from the same art.

15. The Applicant argues that there would be no motivation to attach growth factor to Cahalan because Goldstein uses growth factor in the culture medium. However, this argument is treating Goldstein as if it is the primary reference. Furthermore, this argument fails to treat the rejection as the combination it is. In response to applicant's

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arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

16. The Applicant argues that Robertson does not teach the substrate materials as now set forth in claim 1. This argument is not relevant to the present rejection which has been modified. Furthermore, this argument is against the reference individually where the rejection is based upon a combination.

17. Similarly, Applicant argues against the Bayne rejection in the same manner as in the Robertson (secondary reference) rejection. For the same reasons as used in the previous paragraph, claims 13 and 16 are considered obvious as the prior art is currently applied.

### **Conclusion**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
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